Food and Drug Administration, HHS

food to which nutrients have been added pursuant to paragraph (e) of this section.

[45 FR 6323, Jan. 25, 1980, as amended at 58 FR 2228, Jan. 6, 1993]

Subpart C—Specific Nutritional Quality Guidelines

§ 104.47 Frozen "heat and serve" dinner.

- (a) A product, for which a common or usual name is established in §102.26 of this chapter, in order to be eligible to bear the guideline statement set forth at §104.5(b), shall contain at least the following three components:
- (1) One or more sources of protein derived from meat, poultry, fish, cheese, or eggs.
- (2) One or more vegetables or vegetable mixtures other than potatoes, rice, or cereal-based product.
- (3) Potatoes, rice, or cereal-based product (other than bread or rolls) or another vegetable or vegetable mixture.
- (b) The three or more components named in paragraph (a) of this section, including their sauces, gravies, breading, etc.:
- (1) Shall contribute not less than the minimum levels of nutrients prescribed in paragraph (d) of this section.
- (2) Shall be selected so that one or more of the listed protein sources of paragraph (a)(1) of this section, excluding their sauces, gravies, breading, etc., shall provide not less than 70 percent of the total protein supplied by the components named in paragraph (a) of this section.
- (c) If it is necessary to add any nutrient(s) in order to meet the minimum nutrient levels prescribed in paragraph (d) of this section, the addition of each such nutrient may not result in a total nutrient level exceeding 150 percent of the minimum level prescribed. Nutrients used for such addition shall be biologically available in the final product.
- (d) Minimum levels of nutrients for a frozen "heat and serve" dinner are as follows:

Nutrient	Minimum levels for fro- zen "heat and serve" dinner—	
	For each 100 Cal- ories (keal) of the total compo- nents specified in par. (a)	For the total components specified in par. (a)
Protein, grams	4.60	16.0
Vitamin A, IU	150.00	520.0
Thiamine, mg	.05	.2
Riboflavin, mg	.06	.2
Niacin, mg	.99	3.4
Pantothenic acid, mg	.32	1.1
Vitamin, B ₆ , mg	.15	.5
Vitamin, B ₁	.33	1.1
Iron, mg	.62	2.2

- (1) A frozen "heat and serve" dinner prepared from conventional food ingredients listed in paragraph (a) of this section will also contain folic acid, magnesium, iodine, calcium, and zinc. Minimum levels for these nutrients cannot be established at the present time but may be specified as additional data are obtained.
- (2) The minimum levels for pantothenic acid, vitamin B-6, and vitamin B-12 are tentative. Final levels will be established when sufficient data are available. Until final levels are established, a product containing less than the tentative levels will not be deemed to be misbranded when labeled in accordance with \$104.5(b).
- (3) When technologically practicable, iodized salt shall be used or iodine shall be present at a level equivalent to that which would be present if iodized salt were used in the manufacture of the product.
- (4) When technologically practicable, product components and ingredients shall be selected to obtain the desirable calcium to phosphorous ratio of 1:1. Technological addition of phosphates shall be minimized and shall not exceed the amount necessary for the intended effect.
- (e) If the product includes servings of food which are not prescribed by paragraph (a) of this section (e.g., soup, bread or rolls, beverage, or dessert), their contribution shall not be considered in determining compliance with the nutrient levels established in paragraph (d) of this section but shall be included in any nutrition labeling.

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(f) For the purposes of labeling, an "average serving" shall be one entire frozen "heat and serve" dinner.

[42 FR 14327, Mar. 5, 1977]

PART 105—FOODS FOR SPECIAL DIETARY USE

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AUTHORITY: 21 U.S.C. 321, 341, 343, 348, 350, 371, 379e.

Source: 42 FR 14328, Mar. 15, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 105.3 Definitions and interpretations.

The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (hereafter "the act") shall be applicable with the following additions:

- (a)(1) The term special dietary uses, as applied to food for man, means particular (as distinguished from general) uses of food, as follows:
- (i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;
- (ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;
- (iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless

of whether such food also purports to be or is represented for general use.

- (2) The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics and is therefore a special dietary use.
 - (b)-(d) [Reserved]
- (e) For the purposes of the regulations in this part, the terms *infant*, *child*, and *adult* mean persons not more than 12 months old, more than 12 months but less than 12 years old, and 12 years or more old, respectively.

[42 FR 14328, Mar. 15, 1977, as amended at 44 FR 16006, Mar. 16, 1979; 44 FR 49665, Aug. 24, 1979]

Subpart B—Label Statements

§ 105.62 Hypoallergenic foods.

If a food purports to be or is represented for special dietary use by reason of the decrease or absence of any allergenic property or by reason of being offered as food suitable as a substitute for another food having an allergenic property, the label shall bear:

- (a) The common or usual name and the quantity or proportion of each ingredient (including spices, flavoring, and coloring) in case the food is fabricated from two or more ingredients.
- (b) A qualification of the name of the food, or the name of each ingredient thereof in case the food is fabricated from two or more ingredients, to reveal clearly the specific plant or animal that is the source of such food or of such ingredient, if such food or such ingredient consists in whole or in part of plant or animal matter and such name does not reveal clearly the specific plant or animal that is such a source.
- (c) An informative statement of the nature and effect of any treatment or processing of the food or any ingredient thereof, if the changed allergenic property results from such treatment or processing.